



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,214	03/25/2004	Fiona E. Black	01-00007	2483
29389	7590	04/07/2005	EXAMINER	
ILLUMINA, INC. 9885 TOWNE CENTRE DRIVE SAN DIEGO, CA 92121-1975			LUM, LEON YUN BON	
		ART UNIT	PAPER NUMBER	1641

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/809,214	BLACK ET AL.	
	Examiner	Art Unit	
	Leon Y. Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 July 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 12-33 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-11 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 25 March 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>22 July 2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-11, drawn to a probe composition, classified in class 422, subclass 57.
 - II. Claims 12-14, drawn to a method of making a probe composition, classified in class 435, subclass 287.9.
 - III. Claims 15-32, drawn to a method of detecting a target analyte, classified in class 435, subclass 7.1.
 - IV. Claim 33, drawn to a method of shipping a solid-phase probe, classified in class 224, subclass 101.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process

Art Unit: 1641

(MPEP § 806.05(f)). In the instant case the product as claimed can be made by the materially different process of dip-pen lithography.

3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be practiced by the materially different process of liquid filtration, wherein the biopolymer probe on the substrate binds to analyte in a liquid sample flowing over the substrate, thereby removing the analyte and filtrating the liquid sample.

This relationship also applies to Groups I and IV.

4. Inventions II-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects.

Group II is a method of making a probe composition with the limitation of drying a substrate, which is not a limitation in Groups III-IV.

Group III is a method of detecting a target analyte with the limitations of detecting the presence of a first and second target analyte, which are not limitations in Groups II or IV.

Group IV is a method of shipping a solid-phase probe with the limitation of shipping a package to a remote location, which is not a limitation in Groups II-III.

Therefore, since Groups II-IV each have different modes of operation, different functions, and different effects, they are unrelated inventions.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

In addition, because these inventions are distinct for the reasons given above and the search required for each of Groups I-IV is not required for the other Groups, restriction for examination purposes as indicated is proper.

Group I consists of claims directed towards a product, and Group II consists of claims directed towards a method of making a product, and Groups III-IV consist of claims directed towards a method of using an apparatus. With regards to comparing Groups I and II, searching for a method of making a product does not necessarily encompass all the required searching for the product. Although the product claims may be free of the prior art, the method claims may not be, and would therefore necessitate searching in references not already searched for the product claims. The reverse is also true. In addition, Group I requires searching for an array of particles each attached

Art Unit: 1641

to a patterned surface, which is not a required search for Group II. Group II also requires searching for the step of drying a substrate, which is not a required search for Group I. With respect to differences between Group I and Groups III-IV, Group I requires searching for limitations that are not required for Groups III-IV and vice versa. For example, Group I requires searching for an array of particles each attached to a patterned surface, which is not a required search for Groups III-IV. Group III requires searching for the steps of detecting the presence of a first and second target analyte, and Group IV requires searching for the step of shipping a solid-phase probe with the limitation of shipping a package to a remote location, which are not required searches for Group I. The divergence in searching requirements between Groups II-IV have been disclosed above.

6. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.**

Art Unit: 1641

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. During a telephone conversation with John Murphy on 21 March 2005 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-11. Affirmation of this election must be made by applicant in replying to this

Office action. Claims 12-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

9. The abstract of the disclosure is objected to because it contains the legal phraseology "wherein said" on line 8 of the abstract page. Correction is required. See MPEP § 608.01(b).

10. The disclosure is objected to because of the following informalities: Since Applicant has submitted Figures 1-3 as drawings and has referenced the drawings in the specification on pages 31-39, the specification is required to include a section entitled "Brief Description of Drawings" with a description for each figure. See MPEP § 608.01(f).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. In claim 2, lines 1-2, the phrase "said substrate comprises an array of attached biopolymer probes" is vague and indefinite. The parent claim (claim 1) recites that the substrate and biopolymer probe are two separate embodiments on a probe composition. However, the instant claim states that biopolymer probes comprise the substrate. It is therefore unclear the array of attached biopolymer probes in the instant claim refers to an array of the biopolymer probe of the parent claim, or refers to biopolymer probes that are separate from the biopolymer probe of the parent claim.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1641

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Walt et al (US 6,327,410 B1).

In the instant claims, Walt et al reference teaches a substrate (i.e. substrate) that retains microspheres (i.e. substrate comprises a particle), wherein microsphere 10 has bioactive agent 12 thereon (i.e. biopolymer probe attached to said substrate), and wherein microspheres are placed in wells and a thin film of polyethylene glycol is formed over the microspheres to hold the microspheres in place (i.e. a stabilization polymer layer on said substrate, wherein said stabilization polymer layer coats said biopolymer probe; non-naturally occurring polyethylene glycol). See column 5, line 61 to column 6, line 3; column 7, lines 42-49; column 17, line 47 to column 18, line 2; and Figure 1.

With regards to claims 2, Walt et al reference teaches an array of microspheres 100 formed from microsphere populations that have different bioactive agents (i.e. substrate comprises an array of attached biopolymer probes). See column 15, lines 29-40 and Figure 3.

With regards to claim 3, Walt et al reference teaches that the microsphere array 100 is attached to the distal end 212 of a fiber optic bundle 202 (i.e. substrate comprises a fiber optic array). See column 16, lines 21-29 and Figure 4.

With regards to claims 4-5, Walt et al reference teaches that the microspheres (i.e. particles) are placed in wells, as stated above, and wherein the microspheres are

Art Unit: 1641

covalently attached to the substrate (i.e. an array of particles attached to a patterned surface, wherein the patterned surface comprises wells, each well comprising a single particle of said array of particles). See column 5, line 61 to column 6, line 3; and column 6, lines 48-52.

With regards to claim 7, Walt et al reference teaches that bioactive agents are covalently attached to the beads (i.e. biopolymer probe is covalently attached to said substrate). See column 11, lines 63-64.

With regards to claims 8-9, Walt et al reference teaches that the bioactive agents 12 (i.e. biopolymer) can be polynucleotides or polypeptides. See column 7, line 60 and column 8, line 37.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,544,732 B1 in view of Walt (US 6,327,410 B1).

Claims 1-11 of the instant application recite a probe composition comprising a substrate, a biopolymer probe attached to said substrate, and a stabilization polymer layer on said substrate, wherein said stabilization polymer layer coats said biopolymer probe.

Claims 1-18 of the copending application teaches a substrate (i.e. substrate) with a surface comprising discrete sites, wherein said discrete sites are wells and a population of microspheres comprising a bioactive agent, wherein said microspheres are distributed on said discrete sites (i.e. biopolymer probe attached to said substrate).

However, claims 1-18 of the copending application fail to teach a stabilization polymer layer on said substrate, wherein said stabilization polymer layer coats said biopolymer probe.

Walt et al reference teaches a thin film of polyethylene glycol (i.e. stabilization polymer layer) dripped over microspheres that have been placed in wells, wherein the microspheres include a bioactive agent thereon (i.e. coats said biopolymer probe), in order to fix and hold them in place. See column 7, line 55 to column 8, line 3; and column 17, lines 47 to column 18, line 2.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the composition of claims 1-18 of the copending application with a thin film of polyethylene glycol (i.e. stabilization polymer layer) dripped over

Art Unit: 1641

microspheres that have been placed in wells, wherein the microspheres include a bioactive agent thereon (i.e. coats said biopolymer probe), as taught by Walt et al, in order to fix and hold them in place. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a dripped film of polyethylene glycol over microspheres, as taught by Walt et al, in the composition of claims 1-18 of the copending application, since the copending application teaches microspheres in wells, and the dripped film taught by Walt et al fixes and holds microspheres in wells.

Conclusion

18. No claims are allowed.

19. The prior art made of record and not relied up on is considered pertinent to Applicant's disclosure:

Hargreaves (US 4,868,130) teaches an array of assay vessels, each with a particle for specific binding assays.

Seul (US 6,251,691 B1) teach an array of antibody coated beads for specific binding assays.

Pfost et al (US 6,485,690 B1) teach a multi-layered fluidic array having microbeads in reaction wells.

McDevitt et al (US 6,589,779 B1) teach an array of chemically sensitive particles in cavities.

Hess et al (US 6,716,629) teach an apparatus with an array of particles in individual wells.

Jacobs et al (US 2002/0095073 A1) teach spotting solutions with reagents that help in stabilizing or preserving the biological activity of probes.

Flounders et al (SPIE, vol. 2978, pp. 58-61) teach coating enzyme probes on a substrate with a stabilizer.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leon Y Lum
Patent Examiner
Art Unit 1641



LYL



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

04/01/05